



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,584	06/24/2003	Delma M. Blankenship	ACSC 63079 (3848P)	1260

24201 7590 06/30/2005

FULWIDER PATTON LEE & UTECHT, LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE
TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER

STIGELL, THEODORE J

ART UNIT	PAPER NUMBER
----------	--------------

3763

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,584

Applicant(s)

BLANKENSHIP, DELMA M.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 11, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 15-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/01/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 3763

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-14, drawn to a balloon catheter with a thickened wall portion, classified in class 604, subclass 103.06.
- II. Claims 15-17, drawn to a method of making a balloon catheter, classified in class 156, subclass 195.

Inventions 2 and 1 are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the balloon catheter claimed in Group I could be made by other methods than claimed in Group II such as by adhesion.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Gunther O. Hanke on May 9, 2005 a provisional election was made without traverse to prosecute the invention of a balloon catheter with a thickened wall portion, claims 1-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-

Art Unit: 3763

17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

Claim 7 is objected to because of the following informalities: The term "wherein" should be inserted after the phrase, "The balloon catheter of claim 1". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Crocker et al (5,470,313).

Crocker et al. clearly shows a balloon catheter that includes all of the limitations recited in claim 1. See Figures 1-4 and the respective portions of the specification. Referring to claim 1, Crocker et al. shows a balloon catheter with an elongated shaft (12) having a lumen (32) and a balloon (18) attached to the distal end of shaft (12). The balloon (18) has proximal (37) and distal (39) skirt sections secured to the shaft (12) so that the balloon (18) is in fluid communication with the lumen (32). The balloon (18) has a working length as seen in Figure 2 extending from element (42) to element (46) and proximal and

Art Unit: 3763

distal tapered sections in the tapered regions between the skirt sections and the working length section. The balloon (18) has a first layer (38) formed of a first polymeric material and a second layer comprising elements (36), (40), and (44). Elements (40) and (44) can be made from a variety of polymeric materials including nylon, polyester, and polyimide (col. 4, lines 15-23) so the second layer can be considered to be made of a second polymeric material. The wall thickness of the second layer along the working length section that consists of (36) and (40) and (36) and (44) is greater than the wall thickness along the proximal and distal tapered sections of the second layer in the noninflated configuration. The balloon (18) can have an inflated or noninflated configuration. The figures show the balloon in an inflated configuration but the wall thickness of the second layer would still be greater than the wall thickness of the tapered sections in the noninflated configuration.

In regards to claim 2, Crocker et al. discloses a balloon catheter as recited in claim 1 wherein the wall thickness of the second layer along the working length section that consists of elements (36) and (40) and elements (36) and (44) is greater than the wall thickness of the second layer along both the proximal and distal tapered sections.

In regards to claim 3, Crocker et al. discloses a balloon catheter as recited in claim 2 wherein the working length section has a cylindrical, uniform outer diameter along the entire length of the working length section in an inflated configuration. See Figure 4.

Art Unit: 3763

In regards to claim 4, Crocker et al. discloses a balloon catheter as recited in claim 1 wherein the wall thickness of the second layer along the working length section that consists of elements (36) and (40) and elements (36) and (44) is greater than the wall thickness of the second layer along both skirt sections.

In regards to claim 5, Crocker et al. discloses a balloon catheter as recited in claim 4 wherein the wall thickness of the second layer along the working length section that consists of (36) and (40) and (36) and (44) has two layers so it at least 80% and no more than 120% greater than the wall thickness of the second layer along the proximal skirt section. In the embodiment in Figure 2, the working length section is about 100% greater than the proximal skirt section.

In regards to claim 6, Crocker et al. discloses a balloon catheter as recited in claim 1 wherein the wall thickness of the second layer is substantially uniform along the proximal tapered section.

In regards to claim 7, Crocker et al. discloses a balloon catheter as recited in claim 1 wherein the wall thickness of the second layer is substantially uniform along the distal tapered section.

In regards to claim 9, Crocker et al. discloses a balloon catheter as recited in claim 1 wherein the second layer that consists of elements (36), (40), and (44) is an inner layer relative to the first layer (38).

In regards to claim 12, Crocker et al. discloses a balloon catheter as recited in claim 1 wherein a stent can be mounted on the working length section of the balloon in order to deliver the stent to a vessel in the body (See col.2, lines 31-39).

Art Unit: 3763

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dutta et al. (6,506,202) in view of Horn et al (6,024,752).

Dutta et al. discloses a balloon catheter that includes most of the limitations recited in claims 1-5. See Figures 1-6 and the appropriate sections of the specification. Dutta et al. discloses a balloon catheter with an elongated shaft (28) and a balloon (32) with two layers (36) and (38). The balloon (32) has proximal and distal skirt sections that attach the balloon to the shaft (28), proximal and distal tapered sections that connect the skirt sections to the working section in the middle of the balloon (32). The inner layer (36) can be made from nylon, a PET, or a polyether amide and the second layer (38) can be made from

Art Unit: 3763

another polymeric material usually polyurethane. See col. 6, lines 55-67. The working length of the balloon (32) also has a uniform outer diameter along the entire length of the working section in the inflated configuration. See Figures 1 and 3. Dutta et al. does not teach to make the working length section thicker than the skirt and tapered sections.

Horn et al. discloses a balloon catheter that has one layer with a thickened wall portion along the working length. See Figure 1a and the respective portions of the specification. In regards to claims 1 and 2 the balloon shown in Figs. 1a has a working section (130a) that has a wall thickness greater than the proximal and distal tapered sections (109a) and (122a). In regards to claim 4 the balloon shown in Fig. 1a has a working section (130a) that has a wall thickness greater than the wall thickness of the proximal and distal skirt sections (108a) and (120a). In regards to claim 5 the balloon shown in Fig. 1a has a working section (130a) that has a wall thickness that is at least 80% and no more than 120% greater than the wall thickness of the proximal skirt section (108a). In Fig. 1a the working length section (130a) is about twice as thick as the proximal skirt section (108a) so the working section (130a) is about 100% greater than the proximal skirt section (108a). Horn et al. teaches to make the working length section thicker than the rest of the balloon to make a high strength, less cumbersome balloon that can easily track and cross lesions in the vasculature.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the balloon catheter as disclosed by Dutta et al. with a thickened working length section as disclosed by

Art Unit: 3763

Horn et al. to make a strong, low-profile balloon catheter than can more easily navigate through the body.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker et al. (5,470,313) in view of Simhambatla et al. (WO 01/45766).

Crocker et al. (5,470,313) discloses a balloon catheter that includes most of the limitations as recited in claim 10. Crocker et al. discloses a balloon catheter with an elongated shaft (12) and a balloon (18) disposed on the distal end of the shaft (12). The balloon (18) has proximal and distal skirt sections, proximal and distal tapered sections, and a working length. The balloon has two layers with the second layer defining a thickened wall portion along the working length. The wall thickness of the second layer along portions of the working length is greater than the wall thickness of the second layer along the proximal and distal tapered sections. Crocker et al. does not teach to make the first layer out of a porous polymeric material.

Simhambatla et al. discloses a balloon catheter that is made of two layers. The outer layer (24) is made out of an ultra-high molecular weight polyethylene that is micro-porous and can certainly be considered a porous polymeric material. This helps the balloon expand more rapidly and with less pressure.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a porous polymeric material for the first layer, as disclosed in Simhambatla et al., to make the balloon catheter as disclosed in Crocker et al. so that the balloon catheter would be able to inflate more rapidly and with less pressure.

Art Unit: 3763

Claims 1-4, 6-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dutta et al. (6,506,202) in view of Crocker et al. (5,645,560).

Dutta et al. discloses a balloon catheter that includes most of the limitations recited in claims 1-4, 6-8 and 11. See Figures 1-6 and the appropriate sections of the specification. Dutta et al. discloses a balloon catheter with an elongated shaft (28) and a balloon (32) with two layers (36) and (38). The balloon (32) has proximal and distal skirt sections that attach the balloon to the shaft (28), proximal and distal tapered sections that connect the skirt sections to the working section in the middle of the balloon (32). The working length section has a cylindrical, uniform outer diameter along the entire length of the working section. See Figure 1. The inner layer (36) can be made from nylon, a PET, or a polyether amide and the second layer (38) can be made from another polymeric material usually polyurethane. See col. 6, lines 23-35. The entire second layer is made of the same material. The wall thickness of the second layer (38) is uniform along the proximal and distal tapered sections. Dutta et al. does not teach to make the working length section of the second layer (38) thicker than the skirt and tapered sections of the second layer.

Crocker et al. (5,645,560) discloses a balloon catheter that has a thickened wall along the working length. See Fig. 6 and the respective portions of the specification. The working length is the part of the balloon that extends from element 55 to element 57 as seen in Fig. 6. The wall thickness along sections (52) and (68) of the working length is greater than that of the wall thickness of the proximal and distal tapered sections and the proximal (52) and

Art Unit: 3763

distal (54) skirt sections. The second layer is made thicker by heating sections (52) and (68) which causes layers of the balloon to fuse together to make sections (52) and (68) thicker. See col. 8, lines 20-23. Crocker et al. teaches to make the working length section thicker than the rest of the balloon to make a high strength, less cumbersome balloon that can easily track and cross lesions in the vasculature.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the balloon catheter, as disclosed by Dutta et al., with a thickened working length section, as disclosed by Crocker et al. (5,645,560) to make a strong, low-profile balloon catheter than can more easily navigate through the body.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker et al. (5,470,313) in view of Simhambatla et al. (WO 01/45766).

Crocker et al. discloses a balloon catheter that includes most of the limitations as recited in claim 13. Crocker et al. discloses a balloon catheter with an elongated shaft (12) and a balloon (18) disposed on the distal end of the shaft (12). The balloon (18) has proximal and distal skirt sections, proximal and distal tapered sections, and a working length. The balloon has two layers with the second layer defining a thickened wall portion along the working length. The wall thickness of the second layer along portions of the working length is greater than the wall thickness of the second layer along the proximal and distal skirt sections, and in regards to claim 14 the wall thickness of the second layer along the

Art Unit: 3763

working length is greater than the wall thickness along the proximal and distal tapered sections. Crocker et al. does not teach to make the first layer out of a porous polymeric material and a second layer from another elastomeric polymeric material.

Simhambatla et al. discloses a balloon catheter that is made of two layers. The outer layer (24) is made out of an ultra-high molecular weight polyethylene that is micro-porous and can certainly be considered a porous polymeric material. The inner layer (34) is made of an elastomeric material such as polyurethane. See page 11, lines 8-28. This helps the balloon expand with less resistance at low pressures and much greater resistance at high pressures.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a porous polymeric material for the first layer and another polymeric material for the second layer, as disclosed in Simhambatla et al., to make the balloon catheter as disclosed in Crocker et al. so that the balloon catheter would be more resistant to expansion at higher pressures and thus less likely to burst.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 5,087,394 to Keith
U.S. Patent 5,270,086 to Hamlin
U.S. Patent 5,344,401 to Radisch et al.
U.S. Patent 5,409,495 to Osborn
U.S. Patent 6,124,007 to Wang et al.
U.S. Patent 6,242,063 to Ferrera et al.
U.S. Patent Application 2004/0044309 to Owens et al.

Art Unit: 3763

U.S. Patent Application 2004/0176791 to Lim et al.
U.S. Patent 5,810,871 to Tuckey et al.
U.S. Patent 6,663,614 to Carter
U.S. Patent 6,863,861 to Zhang (Ken) et al.
European Patent 0768097 to Terumo Kabashiki Kaisha
WO 02/081018 to Advanced Cardiovascular Systems

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS



NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700